

Attorney Docket Number: MBIO1999-057CP3RCEMSerial Number: 09/610,118REMARKS

Claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 185, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 233-235, 237, 238, 240, 242, 245-251, 254, and 256-264 were pending in this application as of the final Office Action dated October 21, 2002, and will remain pending upon entry of these remarks. The remarks made herein are designed to place the case in condition for allowance. As such, Applicants respectfully request that the remarks made herein be entered and fully considered.

I. Rejection of Claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 185, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 233-235, 237, 238, 240, 242, 245-251, 254, and 256-264 Under 35 U.S.C. § 112, ¶1- Written Description

Claims 132-136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 155, 157, 159, 161-165, 168, 169, 171, 173, 175-178, 180, 181, 183, 185, 187-189, 191, 192, 194, 196, 198-201, 203, 205, 207, 208, 210-213, 215, 216, 218, 220, 222-224, 226, 227, 229, 233-235, 237, 238, 240, 242, 245-251, 254, and 256-264 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

In response to Applicants' contention that one of skill in the art would be able to ascertain the amino acid sequences of the anti-TANGO 268 antibodies of the invention (comprising one or more V_H CDRs and/or V_L CDRs of the scFc clone A10) by using well known techniques, the Examiner notes that "the instant claims are drawn to an antibody that immunospecifically binds to a human TANGO 268 antigen, and not to an amino acid sequence or combinations thereof" (March 27, 2003 Advisory Action (Paper 26)). Applicants acknowledge that the claims are to antibodies, but antibodies *as defined by* (i) their binding properties (i.e., to epitopes found on their respective antigens (the TANGO 268 proteins of the invention)); and (ii) their amino acid

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sequences (e.g., the amino acid sequences of their constituent complementarity determining regions (CDRs)).

The PTO has published materials that illustrate application of the Written Description Guidelines found in MPEP § 2163, online at www.uspto.gov/web/offices/pac/writtendesc.pdf (hereafter "Application of Guidelines"). As stated in Example 16 of the Application of Guidelines,

"[t]he general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA, and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions. *The sequences of constant regions as well as the variable regions and subgroups (framework regions) from a variety of species are known and published in the art.* It is also well known that antibodies can be made against virtually any protein. (emphasis added)

Because the antibodies of the invention are structurally well characterized (as stated above, and as acknowledged by the Examiner in paragraph two of the Advisory Action), and because the constant regions of the antibodies of the invention are well known and/or can be easily ascertained by employing techniques which are well known in the art (and described in the present application), the Applicants need only provide the amino acid sequences of the *variable regions* (e.g., CDRs) of the antibodies of the invention in order to meet the written description requirement. These sequences are indeed provided on at least page 102 of the present application.

The Examiner agrees with Applicants in paragraph two of the Advisory Action that the antibodies are structurally well characterized, but notes that the antigen binding site is "not taught in the art and is therefore not well known to one of skill in the art at the time the invention was made." Applicants concede that the binding sites (e.g., the CDRs) are not taught in the art, *because this area of novelty is introduced by the Applicants in the present application.* The other portions of the antibodies (e.g., the framework and constant regions) were well known (and well

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characterized) at the time of the filing of the present application, and the CDRs were disclosed at the time of filing (i.e., were described in the present application).

The Examiner, in responding to the Applicants' reference to Example 16 of the Application of Guidelines, notes in the March 27, 2003 Advisory Action (Paper 26) that "the antigen in question, the TANGO 268 antigen, is not novel as evidenced by Applicant's own specification." Applicants presume that the Examiner raises this point in reference to Example 16's clause, "A search of the prior art indicates that antigen X is novel and unobvious."

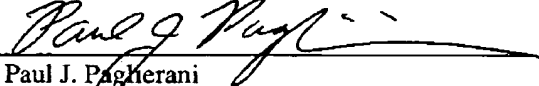
Applicants respectfully traverse the Examiner's application of said Example 16 clause in this context. The TANGO 268 proteins of the invention, which are the antigens to which the antibodies of the present invention bind, *are novel*. Although TANGO 268 is recognized as glycoprotein VI, a protein previously characterized in the art, the Applicants cloned and derived the novel sequence of the gene and its protein, for which they were awarded U.S. patents 6,245,527 (TANGO 268 isolated nucleic acids) and 6,383,779 (TANGO 268 isolated polypeptides). Therefore, the antibodies of the present invention, which bind to novel TANGO 268 proteins, are themselves novel, and therefore, Example 16 of the Application of Guidelines indeed applies.

Because the TANGO 268 proteins are novel, Applicants have therefore provided written description support for antibodies thereto, since, in the words of Example 16, "one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X."

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Applicants respectfully request entry and consideration of the foregoing remarks.
Applicants believe that all of the present claims meet all of the requirements for patentability.
Withdrawal of all rejections is requested.

If any issues remain, the Examiner is requested to telephone the undersigned at (617)
761-6865.

<u>September 22, 2003</u>	<p>MILLENNIUM PHARMACEUTICALS, INC.</p> <p>By <u></u></p> <p>Paul J. Pagherani Registration No. 52,498 75 Sidney Street Cambridge, MA 02139 Telephone - 617-761-6865 Facsimile - 617-551-8820</p>
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